



DEPARTMENT OF HEALTH & HUMAN SERVICES
BUREAU OF PRIMARY HEALTH CARE

Public Health Service

①

DEC 28 2000

Health Resources and
Services Administration
Bethesda MD 20814

Dear Tribe or Tribal Organization:

It has come to our attention that certain outpatient health programs or facilities operated by 638 tribal contractors may be accessing drug discount pricing under section 340B of the Public Health Service Act, 42 U.S.C. § 256b, and are not fully aware of the conditions governing program participation. This program has the potential to confer an enormous health benefit on eligible tribes and tribal organizations in the way of substantial outpatient drug discounts. It is important that all eligible tribes and tribal organizations, participating or considering participating in the 340B Program, be aware of certain program requirements. We believe that all participating tribes and tribal organizations share our respect for the integrity of the 340B Program, and our desire to continue its benefit. We take this opportunity to provide the following clarification of certain issues related to 340B requirements.

Program Background

The 340B Program eligibility requirements for *covered entities* are set forth in section 340B(a)(4) & (5). Section 340B(a)(4)(A) provides threshold eligibility for certain tribes and tribal organizations, eligibility for Federally Qualified Health Centers (FQHCs), as defined by 1905(1)(2)(B) of the Social Security Act (SSA). This provision of the SSA defines a FQHC as including an outpatient health care program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law (P.L.) 93-638) or an urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act (P.L. 94-437) for the provision. See section 340B(a)(4)(I) for separate urban Indian organization authority.

A tribe or tribal organization's eligibility to participate also is contingent upon its compliance with section 340B(a)(5) which enumerates the following program requirements for covered entities: tribes or tribal organizations must not (1) resell or otherwise transfer 340B drugs to individuals who are not its patients or (2) generate a Medicaid rebate on a 340B discounted drug. In addition, a tribe or tribal organization is subject to Departmental and manufacturer audits in order to show compliance with these two requirements. A tribe or tribal organization that is found to have engaged in the proscribed activity will no longer meet the definition of a *covered entity*. The Department has developed program guidelines and rules to interpret 340B provisions and has published these in the *Federal Register* (FR) for notice and comment. See "Duplicate Discounts and Rebates on Drug Purchases," June 23, 1993, 58 FR 34058; "Entity Guidelines," May 13, 1994, 59 FR 25110; "Manufacturer Audit Guidelines and Dispute Resolution Process," December 12, 1996, 61 FR 65406; "Patient and Entity Eligibility," October 24, 1996; 61 FR 55156; and "Contract Pharmacy Services," August 23, 1996, 61 FR 43549. For your convenience, these notices and other helpful information are posted on the 340B Program web site at <http://www.hrsa.gov/odpp>.

(2)

Page 2

Pursuant to section 340B(a)(9) and the manufacturer Pharmaceutical Pricing Agreement (PPA), the Department must notify participating manufacturers and State Medicaid agencies of the identities of all covered entities (e.g., tribes and tribal organizations eligible to participate in the 340B Program). To provide such notice, the Department, through the Health Resources and Services Administration, Office of Pharmacy Affairs, maintains an electronically-posted listing of covered entities. Because section 340B and the PPA also require the Department to identify listed covered entities that no longer meet program eligibility requirements, this list is revised quarterly. Consequently, any tribe or tribal organization must be listed on the 340B Program eligibility list to access 340B discount pricing.

Drug Diversion

Central to program integrity is the prohibition on the unauthorized transfer of 340B drugs, what is termed "drug diversion." Section 340B(a)(5)(B) reads as follows:

(B) PROHIBITING RESALE OF DRUGS.—With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

A participating tribe or tribal organization thus is precluded from transferring 340B drugs to individuals who are not its patients. Given the number and diversity of entities eligible for 340B drug pricing (i.e., covered entities), the definition of a *patient* was developed to assist covered entities in the task of identifying those individuals who could be considered actual patients of the covered entity. The term *patient* was defined in the FR notice entitled "Patient and Entity Eligibility." This definition consists of several criteria, all of which must be satisfied before a participating tribe or tribal organization may dispense a covered drug to an individual:

1. The covered entity has established a **relationship** with the individual, such that the covered entity maintains records of the individual's health care; and
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that **responsibility** for the care provided remains with the covered entity; and
3. The individual receives a health care service or range of services from the covered entity that is consistent with the service or range of services for which grant funding or FQHC look-alike status [638 contract authority] has been provided to the entity.

(3)

Page 3

4. An individual will **not be considered a "patient"** of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

Consequently, a participating tribe or tribal organization may only provide 340B drugs to individuals who are its actual patients (e.g., not just receiving pharmaceuticals).

The Audit Process and Covered Entity Record Keeping

In addition to the interpretation of 340B Program requirements, oversight is maintained through the audit process. A participating tribe or tribal organization may be required to undergo an audit by the Secretary or the drug manufacturer, pursuant to section 340B(a)(5)(C). Such an audit is intended to gauge the tribe or tribal organization's compliance with the prohibitions against drug diversion and the generation of duplicate drug rebates and discounts. Therefore, all participating tribes or tribal organizations should maintain purchasing and dispensing records of 340B drugs and of any claims for Medicaid reimbursement. See the Duplicate Discounts and Rebates FR notice. In addition, the Department's Manufacturer Audit Guidelines, "Suggested Audit Steps," incorporate the record keeping guideline as an integral part of the compliance process, an important safeguard against program abuses. We ask that you review your 340B inventory and accounting procedures now in place to ensure that they comport with the requirements of the 340B Program.

Sanctions for Drug Diversion

The sanctions prescribed for drug diversion underscore the seriousness with which this activity is viewed. If the Secretary finds after notice and a hearing that a covered entity has engaged in drug diversion, the organization would no longer qualify as a covered entity under the law. As a result, the organization would be removed from the eligibility list. Furthermore, the Secretary's finding of drug diversion would render the covered entity liable to drug manufacturers for the amounts of the discounts on those drugs.

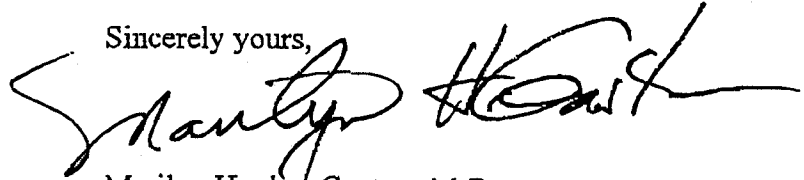
(4)

Page 4

Conclusion

Please take this occasion to review the procedures your tribe or tribal organization now uses or intends to use in complying with the conditions of the 340B Program, in particular those described above. We intend this letter to serve only as a notice of program requirements. The Office of Pharmacy Affairs stands ready to help you with any compliance questions that arise or problems that you may discover. You may call CAPT Jesse Glidewell at (301) 594-4353 for assistance.

Sincerely yours,



Marilyn Hughes Gaston, M.D.

Associate Administrator for Primary Health Care